A randomized trial comparing the CORTRAK system with the endoscopic technique for duodenal feeding tube placement

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Compare the success rate of duodenal feeding tube placement using the CORTRAK system (DFT-C) with the endoscopic technique (DFT-E).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON41400

Source
ToetsingOnline

Brief title
CORRECT study

Condition

- Gastrointestinal conditions NEC

Synonym
duodenul feeding tube placement; feeding tube placement

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: CORPAK MedSystems, Inc, Illinois,

USA,subsidie van CORPAK

Intervention

Keyword: COTRAK, DFT, duodenal feeding tube, endoscopy

Outcome measures

Primary outcome

Success rate of DFT placement; defined as the tip of the tube placed

postpyloric and into the duodenum as confirmed by an abdominal X-ray.

Secondary outcome

Costs associated with DFT placement, procedure time, difficulty of the

procedure, accuracy of tip location with CORTRAK, DFT tip location, safety, use

of sedatives, reintervention rate within 10 days and patient acceptance (in

unsedated patients).

Study description

Background summary

Increasing evidence confirms the important role of enteral feeding in (critically ill) patients. A substantial part of these patients have an indication for duodenal or jejunal feeding. However, duodenal feeding tube (DFT) placement can be difficult, time-consuming, or costly, depending on the technique used. Endoscopic tube placement has high success rates, but the availability of appropriate staff and specialized equipment is required for this technique, making this technique costly and difficult to provide consistently. Several other techniques for DFT placement have been assessed, all require a high level of expertise and most have not been compared with the endoscopic technique. An electromagnetic tube placement device, the CORTRAK system, is increasing in popularity and several observational studies have demonstrated this technique to be safe, efficient, and cost-effective. Only two small studies have compared the CORTRAK system with other placement techniques in a controlled setting.

Study objective

Compare the success rate of duodenal feeding tube placement using the CORTRAK system (DFT-C) with the endoscopic technique (DFT-E).

Study design

Randomized sequential prospective, multicenter, non-blind, controlled trial.

Intervention

Patients will be randomized to undergo DFT placement with the CORTRAK system or the endoscopic technique.

Study burden and risks

The risk for complications when performing DFT placement with the CORTRAK system is probably lower since fewer sedatives will be used. Possible complications are epistaxis, inadvertent passage of the feeding tube into the respiratory tract, aspiration and unsuccessful placement of the feeding tube. There are no guaranteed benefits of participation for the subject, though the burden of participating is negligible. Possible benefits of DFT placement with the CORTRAK system are less need for sedation and less complications due to sedation, cost reduction due to savings on staff and equipment and a simplified logistics that might result in more prompt initiation of enteral feeding with all the benefits of early start of enteral feeding.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- All patients needing a duodenal feeding tube
- Written informed consent provided by patient or representative
- *18 years

Exclusion criteria

- Implantable pacing devices (potential interference with the signal transmission)
- Altered anatomy of the upper gastrointestinal tract due to surgery of the esophagus, stomach or duodenum
- High suspicion of stenosis or obstruction in the upper digestive tract
- Esophageal varices
- Signs of active upper gastrointestinal bleeding.
- Woman with known pregnancy (because of abdominal X-rays performed in order to confirm location of the DFT)

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-12-2013
Enrollment:	309
Type:	Actual

Medical products/devices used

Generic name:	CORTRAK system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-04-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	03-09-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-06-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL42753.041.12